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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/707,262

12/02/2003

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1261

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12/22/2006

EXAMINER

DESAI, ANAND U

ART UNIT

PAPER NUMBER

1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/22/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/707,262	ROBINSON, NOAH E.	
	Examiner	Art Unit	
	Anand U. Desai, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to Amendment filed on August 24, 2006. Claims 1-7 are currently pending and are under examination.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

Applicant is advised of the availability of the publication "Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office." This publication is for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

4. Applicant is encouraged to contact the examiner to schedule an interview for the pending claims upon receipt of this office action.

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Withdrawal of Rejections

5. The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Wright, H. (Protein Engineering Vol. 4, No. 3 pp. 283-294 (1991)) is withdrawn because it does not disclose a method of modifying the neighboring amino acid residues.

Maintenance of Objections and Rejections

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 4-7 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). The claims do not recite any positive method steps to perform to result in the intended use described.

Claim Rejections - 35 USC § 112, 2nd paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
10. Regarding claims 1-4, the phrase "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
11. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: In claims 1-4, a step for measuring the outcome of a modification is missing. How does one know that the deamidation rate has been altered? In claims 5-7, how are the modifications steps performed and then subsequently measured?
12. The term "nearby" in claim 4 is a relative term, which renders the claim indefinite. The term "amide in space" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
13. The metes and bounds of claim 1 is not definite, what "other molecules that contain these amides"?
14. In claim 1, the peptides could encompass the peptide hormones, and therefore it is unclear what hormones are included and excluded with the word, "hormone".
15. Regarding claims 1-7, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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16. Claims 4-7 provide for the use of a technique for changing deamidation rates of Asn and Gln residues in peptides, hormones, proteins and peptide-like, hormone-like, and protein-like molecules, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. Claims are indefinite where they merely recite a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 112, 1st paragraph

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 4-7 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above under the 35 U.S.C. 101 rejection, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, 1st paragraph, written description

19. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are directed to a method for quantitatively changing deamidation rates of Asn and Gln residues in peptides and protein or in other molecules that contain these

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amides, including hormones and drugs and modifications of peptides, proteins, hormones, and drugs.

The claims are rejected under written description, because it is not clear what structural "modifications" of peptides, proteins, hormones, and drugs are being described.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, Paragraph 1, "Written Description" Requirement, published at Federal Register, Vol. 66, No. 4, pp. 1099-1111 outline the method of analysis of claims to determine whether adequate written description is present. The first step is to determine what the claim as a whole covers, i.e., discussion of the full scope of the claim. Second, the application should be fully reviewed to understand how applicant provides support for the claimed invention including each element and/or step, i.e., compare the scope of the claim with the scope of the description. Third, determine whether the applicant was in possession of the claimed invention as a whole at the time of filing. This should include the following considerations: (1) actual reduction to practice, (2) disclosure of drawings or structural chemical formulas, (3) sufficient relevant identifying characteristics such as complete structure, partial structure, physical and/or chemical properties and functional characteristics when coupled with a known or disclosed correlation between function and structure, (4) method of making the claimed invention, (5) level of skill and knowledge in the art and (6) predictability of the art. For each claim drawn to a single embodiment or species, each of these factors is to be considered with regard to that embodiment or species. For each claim drawn to a genus, each of these factors is to be considered to determine whether there is disclosure of a representative number of species that would lead one skilled in the art to conclude that applicant was in possession of the claimed invention. Where

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skill and knowledge in the art is high adequate written description would require fewer species to be disclosed than in an art where little is known; further, more species would need to be disclosed to provide adequate written description for a highly variable genus.

First, what do the claims as a whole cover? Claims 1-4 are directed to a method for quantitatively changing deamidation rates of Asn and Gln residues in modified peptides, proteins, hormones, and drugs.

Second, how does the scope of the claims compare to the scope of the disclosure? The specification is more detailed than claims 1-4. The Tables describe the deamidation of the pentapeptide sequence comprising a core, GlyXxxAsnYyyGly, or GlyXxxGlnYyyGly, wherein the Xxx and Yyy are the 18 other amino acids excluding Asn, and Gln. The claims are directed to the deamidation rates of any modified peptide, protein, hormone, and drug.

Third, the factors need to be considered.

(1) What was actually reduced to practice?

Clearly, the method using pentapeptides in 0.15 M Tris buffer, pH 7.4, at 37 °C shown in Tables 1 and 2 were used to identify the rate of deamidation for pentapeptide sequences.

(2) Is there disclosure of drawings or structural chemical formulas?

Tables 1 and 2 describe the deamidation of the pentapeptide sequences comprising a core, GlyXxxAsnYyyGly, or GlyXxxGlnYyyGly, wherein the Xxx and Yyy are the 18 other amino acids excluding Asn, and Gln.

(3) Are there sufficient relevant identifying characteristics disclosed?

The specification does not disclose the effects of particular modifications on any and all molecules, including modified drugs that one can quantitatively predict the change in deamidation rate for all modified molecules.

(4) Is there at least one method of making the claimed invention disclosed?

One of skill in the art could easily synthesize the polypeptides, since organic solid phase peptide synthesis skills would be needed. Therefore, the deamidation rates of peptides and proteins are described, but the effect of modifications on other molecules are not described.

(5) What is the level of skill in the art and what knowledge is present in the art? /

(6) What is the level of predictability of the art?

Applicants' disclosure states that deamidation rates are affected by a wide variety of parameters, including, pH, Temperature, Ionic Strength, and Buffer Ions. These rates are measured under pH and Temperature conditions that are applicable to biological systems. The buffer type and concentration were chosen to minimize ion affects to the extent possible given the experimental limitations. Modification of these conditions will change the rates in Tables 1 and 2 (see paragraph [0028] of current application, US 20050118674 A1). Therefore level of predictability in this art is very low since, until the structural modification is examined in a particular pH, temperature, or buffer, there is no information upon which to base a prediction of a modified molecules deamidation rates.

Thus, having analyzed the claims with regard to the Written Description guidelines, it is clear that the specification does not disclose a representative number of "modified" peptides, proteins, hormones, and drugs, which would lead one skilled in the art to conclude that applicant was in possession of the claimed invention.

Conclusion

20. No claims are allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

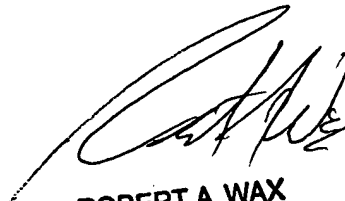
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

December 15, 2006

A handwritten signature in black ink, appearing to be "J. P. D.", located below the date.A handwritten signature in black ink, appearing to be "Robert A. Wax", located above the printed name.

ROBERT A. WAX
PRIMARY EXAMINER